UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2023

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from ___ to ____

Commission File Number: 001-36510

LARIMAR THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**20-3857670**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
Three Bala Plaza East, Suite 506 **Bala Cynwyd, PA**	**19004**
(Address of principal executive offices)	**(Zip Code)**

(844) 511-9056
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	LRMR	The Nasdaq Global Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of August 7, 2023, there were 43,277,500 shares of the registrant's Common Stock, $0.001 par value per share, outstanding.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements made in this Quarterly Report on Form 10-Q that are not statements of historical or current facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements discuss our business, operations and financial performance and conditions, as well as our plans, objectives and expectations for our business operations and financial performance and condition. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “design,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “positioned,” “potential,” “seek,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. In addition, statements that “we believe” or similar statements reflect our beliefs and opinions on the relevant subject only. These forward-looking statements, which are subject to risks, uncertainties and assumptions about us, may include projections of our future financial performance, our anticipated growth strategies and anticipated trends in our business.

You should understand that the following important factors could affect our future results and could cause those results or other outcomes to differ materially from those expressed or implied in our forward-looking statements:

- uncertainties in obtaining successful non-clinical or clinical results that reliably and meaningfully demonstrate safety, tolerability and efficacy profiles that are satisfactory to the U.S. Food and Drug Administration (“FDA”), European Medicines Agency and other comparable regulatory authorities for marketing approval for CTI-1601 or any other product candidate that we may develop in the future and unexpected costs that may result therefrom;
- delays in patient recruitment for our clinical trials (including as a result of the impact of FDA approval of competitive products for the treatment of Friedreich's ataxia ("FA"), and/or the impact of other clinical trials of competitive products), delays as a result of clinical and non-clinical results and/or FDA's request for additional information or studies, changes in clinical protocols, regulatory restrictions, including additional clinical holds, and milestones for CTI-1601;
- our ability to successfully initiate and complete the 50 mg cohort of our four-week, placebo-controlled, Phase 2 dose exploration trial of CTI-1601 and our ability to initiate the open label extension trial and engage with and satisfactorily respond to questions from the FDA regarding future submissions of data from each such trial, and the FDA’s agreement to allow us to perform additional cohorts and/or initiate other clinical trials for CTI-1601 and the timing and outcomes of such interactions;
- uncertainties associated with the clinical development and regulatory approval for CTI-1601 or any other product candidate that we may develop in the future, including potential delays in the commencement, enrollment and completion of clinical trials;
- the difficulties and expenses associated with obtaining and maintaining regulatory approval for CTI-1601 or any other product candidate we may develop in the future, and the indication and labeling under any such approval;
- our estimates regarding future results of operations, financial position, research and development costs, capital requirements and our access and needs for additional financing;
- how long we can continue to fund our operations with our existing cash, cash equivalents and marketable securities;
- our ability, and the ability of third-party manufacturers we engage, to optimize and scale CTI-1601 or any other product candidate’s manufacturing process and to manufacture sufficient quantities of clinical supplies, and, if approved, commercial supplies of CTI-1601 or any other product candidate that we may develop in the future;
- our ability to realize any value from CTI-1601 and/or any other product candidate we may develop in the future in light of inherent risks and difficulties involved in successfully bringing product candidates to market and the risk that the product candidates, if approved, will not achieve broad market acceptance;

- our ability to comply with regulatory requirements applicable to our business and other regulatory developments in the United States and other countries;
- the size and growth of the potential markets for CTI-1601, if approved, or any other product candidate that we may develop in the future, the rate and degree of market acceptance of CTI-1601 or any other product candidate, if approved, that we may develop in the future and our ability to serve those markets;
- given competing therapies and products for the treatment of FA, our ability to obtain and maintain designations or eligibility for expedited regulatory programs, and to commercialize current and future candidates, if approved, (including the impact of potential barriers to entry if a competitor is able to establish a strong market position before we are able to commercialize our products);
- our ability to obtain and maintain patent protection and defend our intellectual property rights against third-parties;
- the performance and compliance with the rules and regulations of the FDA (and all other regulatory authorities) of third parties upon which we depend, including third-party contract research organizations ("CROs"), consultants, and third-party suppliers, manufacturers, distributors, and logistics providers;
- our ability to maintain our relationships, and contracts with our key vendors and to identify and contract with alternate or secondary key vendors;
- our ability to recruit and retain key scientific, technical, commercial, and management personnel and to retain our executive officers;
- our ability to maintain proper functionality and security of our internal computer and information systems and prevent or avoid cyber-attacks, malicious intrusion, breakdown, destruction, loss of data privacy or other significant disruption;
- the extent to which geopolitical tensions, adverse macroeconomic events, including those due to inflationary pressures, rising interest rates, banking instability and the ability of the U.S. government to manage federal debt limits, health epidemics, unforeseen emergencies and other outbreaks of communicable diseases could disrupt our operations, the operations of third parties on which we rely or the operations of regulatory agencies we interact with in the development of CTI-1601; and
- the potential impact of healthcare reform in the United States, including the Inflation Reduction Act of 2022, and measures being taken worldwide designed to reduce healthcare costs and limit the overall level of government expenditures.

These forward-looking statements are based on management’s current expectations, estimates, forecasts and projections about our business and the industry in which we operate. Management’s beliefs and assumptions are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Although we believe the expectations reflected in the forward-looking statements are reasonable, the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements may not be achieved or occur at all. The factors that could cause or contribute to such differences include, but are not limited to, those discussed in our Annual Report on Form 10-K filed on March 14, 2023 and our Quarterly Report on Form 10-Q filed on May 15, 2023. All forward-looking statements are applicable only as of the date on which they were made and, except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this Quarterly Report on Form 10-Q or to reflect the occurrence of any unanticipated events. Comparisons of results for current and any prior periods are not intended to express any future trends or indications of future performance, unless expressed as such, and should only be viewed as historical data.

Larimar Therapeutics, Inc.

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PART I-FINANCIAL INFORMATION

Item 1. Financial Statements

LARIMAR THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)
(Unaudited)

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 94,321	$ 26,825
Marketable securities	9,879	91,603
Prepaid expenses and other current assets	2,278	2,311
Total current assets	106,478	120,739
Property and equipment, net	677	831
Operating lease right-of-use assets	2,578	2,858
Restricted cash	1,339	1,339
Other assets	644	638
Total assets	$ 111,716	$ 126,405
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,344	$ 1,686
Accrued expenses	4,365	8,408
Operating lease liabilities, current	566	611
Total current liabilities	7,275	10,705
Operating lease liabilities	4,511	4,797
Total liabilities	11,786	15,502
Commitments and contingencies (See Note 8)		
Stockholders' equity:		
Preferred stock; $0.001 par value per share; 5,000,000 shares authorized as of June 30, 2023 and December 31, 2022; no shares issued and outstanding as of June 30, 2023 and December 31, 2022	—	—
Common stock, $0.001 par value per share; 115,000,000 shares authorized as of June 30, 2023 and December 31, 2022; 43,269,200 shares issued and outstanding as of June 30, 2023 and December 31, 2022	43	43
Additional paid-in capital	266,372	262,496
Accumulated deficit	(166,497)	(151,605)
Accumulated other comprehensive gain (loss)	12	(31)
Total stockholders' equity	99,930	110,903
Total liabilities and stockholders' equity	$ 111,716	$ 126,405

The accompanying notes are an integral part of these condensed consolidated financial statements.

LARIMAR THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 5,875	$ 5,644	$ 10,437	$ 11,450
General and administrative	3,745	3,043	6,820	6,124
Total operating expenses	9,620	8,687	17,257	17,574
Loss from operations	(9,620)	(8,687)	(17,257)	(17,574)
Other income (expense), net	1,254	20	2,365	(36)
Net loss	$ (8,366)	$ (8,667)	$ (14,892)	$ (17,610)
Net loss per share, basic and diluted	$ (0.19)	$ (0.47)	$ (0.34)	$ (0.96)
Weighted average common shares outstanding, basic and diluted	43,897,603	18,338,853	43,897,603	18,338,853
Comprehensive loss:				
Net loss	$ (8,366)	$ (8,667)	$ (14,892)	$ (17,610)
Other comprehensive gain (loss):				
Unrealized gain (loss) on marketable securities	12	(57)	43	(57)
Total other comprehensive gain (loss)	12	(57)	43	(57)
Total comprehensive loss	$ (8,354)	$ (8,724)	$ (14,849)	$ (17,667)

The accompanying notes are an integral part of these condensed consolidated financial statements.

LARIMAR THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(In thousands, except share data)
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Gain (Loss)	Total Stockholders' Equity
	Shares	Par Value				
Balances as of December 31, 2022	43,269,200	$ 43	$ 262,496	$ (151,605)	$ (31)	$ 110,903
Stock-based compensation expense	—	—	1,833	—	—	1,833
Unrealized gain on marketable securities	—	—	—	—	31	31
Net loss	—	—	—	(6,526)	—	(6,526)
Balances as of March 31, 2023	43,269,200	$ 43	$ 264,329	$ (158,131)	$ —	$ 106,241
Stock-based compensation expense	—	—	2,043	—	—	2,043
Unrealized gain on marketable securities	—	—	—	—	12	12
Net loss	—	—	—	(8,366)		(8,366)
Balances as of June 30, 2023	43,269,200	$ 43	$ 266,372	$ (166,497)	$ 12	$ 99,930

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Par Value				
Balances as of December 31, 2021	17,710,450	$ 18	$ 180,645	$ (116,250)	$ —	$ 64,413
Stock-based compensation expense	—	—	1,635	—	—	1,635
Net loss	—	—	—	(8,943)	—	(8,943)
Balances as of March 31, 2022	17,710,450	$ 18	$ 182,280	$ (125,193)	$ —	$ 57,105
Stock-based compensation expense	—	—	1,675	—	—	1,675
Unrealized loss on marketable securities	—	—	—	—	(57)	(57)
Net loss	—	—	—	(8,667)	—	(8,667)
Balances as of June 30, 2022	17,710,450	$ 18	$ 183,955	$ (133,860)	$ (57)	$ 50,056

The accompanying notes are an integral part of these condensed consolidated financial statements.

LARIMAR THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Six Months Ended June 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (14,892)	$ (17,610)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	3,876	3,310
Non-cash lease expense	(51)	(15)
Depreciation expense	154	163
Amortization of premium on marketable securities	(645)	(3)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	33	287
Accounts payable	658	(1,235)
Accrued expenses	(4,043)	64
Other assets	(6)	20
Net cash used in operating activities:	(14,916)	(15,019)
Cash flows from investing activities:		
Purchase of property and equipment	—	(100)
Purchase of marketable securities	(9,847)	(35,242)
Maturities and sales of marketable securities	92,259	—
Net cash provided by (used in) investing activities	82,412	(35,342)
Cash flows from financing activities:	—	—
Net cash provided by financing activities	—	—
Net increase (decrease) in cash, cash equivalents and restricted cash	67,496	(50,361)
Cash, cash equivalents and restricted cash at beginning of period	28,164	71,436
Cash, cash equivalents and restricted cash at end of period	$ 95,660	$ 21,075

The accompanying notes are an integral part of these condensed consolidated financial statements.

1. Description of Business and Basis of Presentation

Larimar Therapeutics, Inc., together with its subsidiary (the “Company” or “Larimar”), is a clinical-stage biotechnology company focused on developing treatments for patients suffering from complex rare diseases using its novel cell penetrating peptide technology platform. Larimar's lead product candidate, CTI-1601, is a subcutaneously administered, recombinant fusion protein intended to deliver human frataxin ("FXN"), an essential protein, to the mitochondria of patients with Friedreich’s ataxia ("FA"). FA is a rare, progressive and fatal disease in which patients are unable to produce sufficient FXN due to a genetic abnormality.

The Company has completed two phase 1 studies of CTI-1601 and the first cohort of a Phase 2 in patients with FA. In May 2021, after reporting positive top-line data from the Company’s Phase 1 FA program, the U.S. Food and Drug Administration (“FDA”) placed a clinical hold on the Company’s CTI-1601 clinical program after the Company notified the Agency of mortalities at the highest dose levels of a 26-week non-human primate toxicology study that was designed to support extended dosing of patients with CTI-1601. In August 2022, the Company submitted a complete response to the clinical hold, following a Type C Meeting with the FDA, and proposed as CTI-1601’s next clinical trial a Phase 2, four-week, dose exploration study in FA patients starting at the lower dose levels tested in the Company’s Phase 1 multiple-ascending dose clinical trial. In September 2022, the FDA lifted its full clinical hold on the CTI-1601 program and imposed a partial clinical hold.

In May 2023, the Company announced top-line data from its completed a 25 mg cohort of a Phase 2, four-week, dose exploration trial of CTI-1601 in patients with FA and provided a complete response to the FDA in June 2023, which included unblinded safety, pharmacokinetic ("PK"), and pharmacodynamic data from the Phase 2 trial’s completed 25 mg cohort. Data from the completed 25 mg cohort (n = 13) indicated that CTI-1601 was generally well tolerated and showed increases in FXN levels from baseline compared to placebo in all evaluated tissues (skin and buccal cells) at day 14 (the final day of daily dosing in the trial). In June 2023, the Company met with the FDA. Following that meeting, the Company submitted a complete response to the FDA’s partial clinical hold that included unblinded safety, pharmacokinetic (“PK”) and frataxin data from the Phase 2 trial’s completed 25 mg cohort.

In July 2023, the FDA cleared the Company’s four-week, placebo-controlled, Phase 2 dose exploration trial of CTI-1601 in patients with FA to proceed to a 50 mg cohort in which participants will be dosed daily for the first 14 days, and then every other day until day 28. Additionally, the FDA cleared for initiation the Company’s open label extension (“OLE”) trial in which participants will receive 25 mg of CTI-1601 daily. Further dose escalation in the Phase 2 and OLE trials and the initiation of additional U.S. clinical trials evaluating CTI-1601 are contingent on FDA review of results from the Phase 2 trial’s 50 mg cohort in accordance with a partial clinical hold.

The Company is subject to risks and uncertainties common to pre-commercial companies in the biotechnology industry, including, but not limited to, development and commercialization by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with governmental regulations, failure to secure regulatory approval for its drug candidates or any other product candidates and the ability to secure additional capital to fund its operations. Product candidates currently under development will require extensive non-clinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel, infrastructure and extensive compliance-reporting capabilities. Even if the Company's drug development efforts are successful, it is uncertain when, if ever, it will realize significant revenue from product sales.

Basis of Presentation

The condensed consolidated financial statements include the accounts of Larimar and its wholly owned subsidiary. All intercompany balances and transactions have been eliminated. The accompanying condensed consolidated financial statements have been prepared in conformity with Generally Accepted Accounting Principles ("GAAP").

The condensed consolidated balance sheet as of December 31, 2022 was derived from the Company’s audited financial statements but does not include all disclosures required by GAAP. The accompanying unaudited condensed consolidated financial statements as of June 30, 2023 and for the three and six months ended June 30, 2023 and 2022, have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission (“SEC”) for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. However, the Company believes that the disclosures are adequate to make the

information presented not misleading. These condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the year ended December 31, 2022 included in the Company's Annual Report on Form 10-K filed with the SEC on March 14, 2023 and the Company's Quarterly Report on Form 10-Q filed with the SEC on May 15, 2023.

In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company's condensed consolidated financial position as of June 30, 2023, condensed consolidated results of operations for the three and six months ended June 30, 2023 and 2022 and condensed consolidated statement of cash flows for the six months ended June 30, 2023 and 2022 have been made. The results of operations for the three and six months ended June 30, 2023 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2023.

Liquidity and Capital Resources

The Company's condensed consolidated financial statements have been presented on the basis that it will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business.

Since its inception, the Company has incurred significant recurring operating losses and negative cash flows from operations. The Company has incurred net losses of $14.9 million and $17.6 million for the six months ended June 30, 2023 and 2022, respectively. In addition, as of June 30, 2023, the Company had an accumulated deficit of $166.5 million. The Company expects to continue to generate operating losses for the foreseeable future. As of June 30, 2023, the Company had approximately $104.2 million of cash, cash equivalents and marketable securities available for use to fund its operations and capital requirements.

The Company has funded its operations to date primarily with proceeds from sales of common stock and proceeds from the sale of prefunded warrants for the purchase of common stock, the acquisition in 2020 of cash, cash equivalents, marketable securities and restricted cash upon the merger with Zafgen, Inc. ("Zafgen") and, prior to the 2020 merger with Zafgen, capital contributions from Chondrial Holdings, LLC.

In accordance with Accounting Standards Update ("ASU") No. 2014-15, "*Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*", the Company has evaluated whether there are certain conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that these condensed consolidated financial statements are issued. As of the issuance date of these condensed consolidated financial statements, the Company expects its cash, cash equivalents and marketable securities will be sufficient to fund its forecasted operating expenses and capital expenditure requirements, for at least twelve months from the issuance of these condensed consolidated financial statements. If the timing of the Company's clinical assumptions are delayed or if there are other forecasted assumption changes that negatively impact its operating plan, the Company could reduce expenditures in order to further extend cash resources.

The Company has not yet commercialized any products and does not expect to generate revenue from the commercial sale of any products for several years, if at all. The Company expects that its research and development and general and administrative expenses will continue to increase and, as a result, that it will need additional capital to fund its future operating and capital requirements. Unless and until the Company can generate substantial revenue, management continuously evaluates different strategies to obtain the required funding for future operations. These strategies include seeking additional funding through a combination of public or private equity offerings, debt financings, collaborations and licensing arrangements, strategic partnerships with pharmaceutical and/or larger biotechnology companies, or other sources. The incurrence of indebtedness would result in increased fixed payment obligations and the Company may be required to agree to certain restrictive covenants, such as limitations on its ability to incur additional debt, limitations on its ability to acquire, sell or license intellectual property rights, minimum required cash balances and other operating restrictions that could adversely impact the Company's ability to conduct its business. Any additional fundraising efforts may divert the Company's management from their day-to-day activities, which may adversely affect its ability to develop and commercialize its product candidates.

There can be no assurance that the Company will be able to raise sufficient additional capital on acceptable terms, if at all. If such additional financing is not available on satisfactory terms, or is not available in sufficient amounts, or if the Company does not have sufficient authorized shares, the Company may be required to delay, limit, or eliminate the development of business opportunities and its ability to achieve its business objectives, its competitiveness, and its business, financial condition, and results of operations will be materially adversely affected.

The Company could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and it may be required to relinquish rights to some of its technologies or product candidates or otherwise agree to terms unfavorable to it, any of which may have a material adverse effect on the Company's business, operating results and prospects. In addition, geopolitical tensions, volatility of capital markets, and other adverse macroeconomic events, including those due to inflationary pressures, rising interest rates, bank instability and the ability of the U.S. government to manage federal debt limits as well as the potential impact of other health crises on the global financial markets may reduce the Company's ability to access capital, which could negatively affect its liquidity and ability to continue as a going concern.

If the Company is unable to obtain sufficient funding when needed and/or on acceptable terms, the Company may be required to significantly curtail, delay or discontinue one or more of its research and development programs, the manufacture of clinical and commercial supplies, product portfolio expansion or pre commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Significant estimates and assumptions reflected in these condensed consolidated financial statements include, but are not limited to, the accrual of research and development expense, the recording as prepaid expense of payments made in advance of the actual provision of goods or services, valuation of stock-based awards and valuation of leases. Due to inherent uncertainty involved in making estimates, actual results reported in future periods may be affected by changes in these estimates. On an ongoing basis, the Company evaluates its estimates and assumptions.

Research and Development Costs

Costs associated with internal research and development and external research and development services, including drug development, clinical studies and non-clinical studies, are expensed as incurred. Research and development expenses include costs for salaries, employee benefits, subcontractors, stock-based compensation, facility-related expenses, third-party license fees, laboratory supplies, and external costs of outside vendors engaged to conduct discovery, non-clinical and clinical development activities, and clinical trials as well as to manufacture clinical trial materials, depreciation and other costs. The Company recognizes external research and development costs based on an evaluation of the progress to completion of specific tasks using information provided to the Company by its service providers.

Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such prepaid expenses are recognized as an expense when the goods have been delivered or the related services have been performed, or when it is no longer expected that the goods will be delivered, or the services rendered.

Upfront payments, milestone payments and annual maintenance fees under license agreements are currently expensed in the period in which they are incurred.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

Stock-Based Compensation

The Company measures all stock-based awards granted to employees and directors based on the fair value on the date of grant using the Black-Scholes option-pricing model. Compensation expense of those awards is recognized over the requisite service period, which is the vesting period of the respective award. Typically, the Company issues awards with only service-based vesting conditions and records the expense for these awards using the straight-line method. The Company accounts for forfeitures as they occur.

The Company classifies stock-based compensation expense in its condensed consolidated statements of operations and comprehensive loss in the same manner in which the award recipient’s payroll costs are classified or in which the award recipient’s service payments are classified.

Prior to May 28, 2020, the Company had been a private company and lacked company-specific historical and implied volatility information for its common stock. Prior to January 1, 2023, the Company estimated its expected common stock price volatility solely based on the historical volatility of publicly traded peer companies. Beginning on January 1, 2023, based on the availability of sufficient historical trading data of the Company's own common stock on the Nasdaq Global Market to calculate accurately its volatility, the Company began blending its volatility starting from June 2020 (following its merger with Zafgen in 2020) to the date of each stock-based award, and weighing the volatility of its peer group for the amount of time from May 31, 2020 backwards so that the blended volatility equals the expected term of the related stock-based award. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The expected dividend yield considers the fact that the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future.

Net Loss Per Share

Basic net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period. Basic shares outstanding includes the weighted average effect of the Company's prefunded warrants issued in June 2020, the exercise of which requires little or no consideration for the delivery of shares of common stock. Basic and diluted weighted average shares of common stock outstanding for the three and six months ended June 30, 2023 and 2022 includes the weighted average effect of 628,403 prefunded warrants for the purchase of shares of common stock, for which the remaining unfunded exercise price is $0.01 per share.

Diluted net loss per share attributable to common stockholders is computed by dividing the diluted net loss attributable to common stockholders by the weighted average number of common shares, including potentially dilutive common stock equivalents assuming the dilutive effect of outstanding stock options, outstanding restricted stock units, and unvested restricted common shares, as determined using the treasury stock method. For periods in which the Company has reported net losses (all periods since inception), diluted net loss per common share attributable to common stockholders is the same as basic net loss per common share attributable to common stockholders, since dilutive common stock equivalents are not assumed to have been issued if their effect is antidilutive.

The Company excluded 5,129,327 and 3,130,370 common stock equivalents outstanding as of June 30, 2023 and 2022, respectively, from the computation of diluted net loss per share for the three and six months ended June 30, 2023 and 2022 because they had an anti-dilutive impact due to the net loss incurred for the periods presented.

Recently Issued and Adopted Accounting Pronouncements

From time to time, new accounting guidance is issued by the FASB or other standard setting bodies that is adopted by us as of the effective date or, in some cases where early adoption is permitted, in advance of the effective date. We have assessed the recently issued guidance that is not yet effective and believe the new guidance will not have a material impact on the condensed consolidated results of operations, cash flows or financial position.

3. Fair Value Measurements and Marketable Securities

Fair Value Measurements

The Company's assets and liabilities that are measured at fair value on a recurring basis as of June 30, 2023 and December 31, 2022 are measured in accordance with the standards of ASC 820, "*Fair Value Measurements and Disclosures*", which establishes a three-level valuation hierarchy for measuring fair value and expands financial statement disclosures about fair value measurements. The valuation hierarchy is based on the transparency of inputs to the valuation of an asset or liability as of the measurement date. The three levels are defined as follows:

Level – 1	Inputs to the valuation methodology are quoted prices (unadjusted) for identical assets or liabilities in active markets.
Level – 2	Inputs to the valuation methodology include quoted prices for similar assets and liabilities in active markets, and inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the financial instrument.
Level – 3	Inputs to the valuation methodology are unobservable and significant to the fair value measurement.

The Company's financial instruments consist primarily of cash, cash equivalents, marketable securities, accounts payable and accrued liabilities. For accounts payable and accrued liabilities, the carrying amounts of these financial instruments as of June 30, 2023 and December 31, 2022 were considered representative of their fair values due to their short term to maturity.

The following tables summarize the Company's cash equivalents and marketable securities as of June 30, 2023 and December 31, 2022.

	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
		(in thousands)		
June 30, 2023				
Cash equivalents:				
Money market funds invested in government securities	$ 58,729	$ 58,729	$ —	$ —
U.S Treasury bills	25,758	25,758	—	—
Corporate bonds	7,889	—	7,889	—
Total cash equivalents	92,376	84,487	7,889	—
Marketable securities:				
U.S Treasury bills	9,879	9,879	—	—
Total marketable securities	9,879	9,879	—	—
Total cash equivalents and marketable securities	$ 102,255	$ 94,366	$ 7,889	$ —
December 31, 2022				
Cash equivalents:				
Money market funds invested in government securities	$ 22,184	$ 22,184	$ —	$ —
Total cash equivalents	22,184	22,184	—	—
Marketable securities:				
U.S Government and agency securities	91,603	—	91,603	—
Total marketable securities	91,603	—	91,603	—
Total cash equivalents and marketable securities	$ 113,787	$ 22,184	$ 91,603	$ —

The accrued interest receivable related to the Company's investments was $0.3 million and $0.1 million as of June 30, 2023 and December 31, 2022, respectively, and is included in prepaid expenses and other current assets on the condensed consolidated balance sheet.

The Company classifies its money market funds and U.S. treasury bills, which are valued based on quoted market prices in active markets with no valuation adjustment, as Level 1 assets within the fair value hierarchy.

The Company classifies its investments in U.S. government and agency securities, corporate commercial paper, and corporate bonds, if any, as Level 2 assets within the fair value hierarchy. The fair values of these investments are estimated by taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads, benchmark securities, prepayment/default projections based on historical data and other observable inputs.

As of December 31, 2022, the unrealized losses for available-for-sale investments were non-credit related, and the Company does not intend to sell the investments that were in an unrealized loss position, nor will it be required to sell those investments before recovery of their amortized cost basis, which may be maturity. As of June 30, 2023 and December 31, 2022, no allowances for credit losses for the Company's investments were recorded. During the

three and six months ended June 30, 2023 and 2022, the Company did not recognize any impairment losses related to investments.

Marketable securities

The following table summarizes the Company's marketable securities as of June 30, 2023 and December 31, 2022.

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)			
June 30, 2023				
Assets:				
U.S Treasury bills	$ 9,876	$ 3	$ —	$ 9,879
Total marketable securities	$ 9,876	$ 3	$ —	$ 9,879
December 31, 2022				
Assets:				
U.S Government and agency securities	$ 91,634	$ 12	$ (43)	$ 91,603
Total marketable securities	$ 91,634	$ 12	$ (43)	$ 91,603

4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	June 30, 2023	December 31, 2022
	(in thousands)	
Prepaid research and development expenses	$ 1,640	$ 1,394
Prepaid insurance	152	679
Other prepaid expenses and other assets	486	238
	$ 2,278	$ 2,311

5. Fixed Assets

Fixed assets, net consisted of the following:

	Useful Life	June 30, 2023	December 31, 2022
		(in thousands)	
Computer equipment	5 years	$ 66	$ 66
Lab equipment	5 years	1,192	1,192
Furniture and fixtures	7 years	456	456
Leasehold improvements	lease term	31	31
		1,745	1,745
Less: Accumulated depreciation		(1,068)	(914)
		$ 677	$ 831

Depreciation expense was $0.1 million and $0.2 million for the three and six months ended June 30, 2023, respectively. Depreciation expense was $0.1 million for the three and six months ended June 30, 2022, respectively. In addition, for the three and six months ended June 30, 2023, there was less than $0.1 million and $0.1 million, respectively, of depreciation related to sublet assets recorded as other expense. For the three and six months ended June 30, 2022, there was less than $0.1 million and $0.1 million, respectively, of depreciation related to sublet assets recorded as other expense.

6. Accrued Expenses

	June 30, 2023	December 31, 2022
	(in thousands)	
Accrued research and development expenses	$ 2,484	$ 5,921
Accrued payroll and related expenses	1,046	2,046
Accrued other	835	441
	$ 4,365	$ 8,408

7. Stockholders' Equity and Stock Options

Common Stock and Prefunded Warrants

On May 28, 2020, the Company entered into a securities purchase agreement with certain accredited investors (the "Purchasers") for the sale by the Company in a private placement of 6,105,359 shares of the Company's common stock and prefunded warrants to purchase an aggregate of 628,403 shares of the Company's common stock, for a price of $11.88 per share of the common stock and $11.87 per prefunded warrant. The prefunded warrants are exercisable at an exercise price of $0.01 and are exercisable indefinitely. The Purchasers may exercise the prefunded warrants on a cashless basis in the event that there is no effective registration statement covering the resale of the shares of common stock underlying the prefunded warrants on the date in which the Company is required to deliver the shares. The private placement closed on June 1, 2020. The aggregate gross proceeds for the issuance and sale of the common stock and prefunded warrants were $80.0 million; transaction costs totaled $4.6 million and resulted in net proceeds of $75.4 million. The Company's Registration Statement on Form S-3, filed with the SEC on June 26, 2020, registered the resale of 6,105,359 shares of common stock sold and the 628,403 shares of common stock underlying the prefunded warrants. MTS Health Partners served as placement agent to the Company in connection with the private placement. As partial compensation for these services, the Company issued MTS Health Partners 35,260 shares of common stock.

As of June 30, 2023, the Company's Certificate of Incorporation, as amended and restated, authorized the Company to issue up to 115,000,000 shares of $0.001 par value common stock, of which 43,269,200 shares were issued and outstanding, and up to 5,000,000 shares of $0.001 par value undesignated preferred stock, of which no shares were issued or outstanding. The voting, dividend, and liquidation rights of the holders of the Company's common stock are subject to and qualified by the rights, powers, and preferences of the holders of the preferred stock, if any. Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the board of directors of the Company (the "Board"), if any. No cash dividends have been declared or paid to date.

In September 2022, the Company sold 25,558,750 shares of common stock at a public offering price of $3.15 per share and received net proceeds, net of underwriting discounts and commissions and offering costs of $75.2 million.

2022 ATM Agreement

On November 10, 2022, the Company entered into a sales agreement (the "ATM Agreement") with Guggenheim Securities, LLC in connection with the establishment of an "at-the-market" offering program under which the Company may sell up to an aggregate of $50.0 million of shares of common stock (the "ATM Shares") from time to time.

Under the ATM Agreement, the Company sets the parameters for the sale of ATM Shares, including the number of ATM Shares to be issued, the time period during which sales are requested to be made, limitations on the number of ATM Shares that may be sold in any one trading day and any minimum price below which sales may not be made. Sales of the ATM Shares, if any, under the ATM Agreement may be made in transactions that are deemed to be "at-the-market offerings" as defined in Rule 415 under the Securities Act. The Company pays its investment bank a commission equal to 3.0% of the gross proceeds of any ATM Shares sold through its investment bank under the ATM Agreement and reimburses the investment bank for certain specified expenses. The ATM Agreement contains customary representations, warranties and agreements by the Company, indemnification obligations of the Company and its investment bank, other customary obligations of the parties and termination provisions. The Company has no obligation to sell any of the ATM Shares and may at any time suspend offers under the ATM Agreement.

The ATM Shares will be offered and sold pursuant to the Company's Registration Statement on Form S-3, filed by the Company on November 10, 2022 and effective as of November 21, 2022 (the "Registration Statement"), and the sales agreement prospectus that forms a part of such Registration Statement. As of the date of this Quarterly Report on Form 10-Q, no ATM Shares have been sold pursuant to the ATM Agreement.

2020 Equity Incentive Plan

The Board adopted the 2020 Equity Incentive Plan (the "2020 Plan") on July 16, 2020 and the stockholders of the Company approved the 2020 Plan on September 29, 2020. The 2020 Plan replaces the predecessor plans (the "Prior Plans") that the Company assumed following its merger with Zafgen in May 2020. Options outstanding under the Prior Plans will remain outstanding, unchanged, and subject to the terms of the Prior Plans and the respective award agreements, and no further awards will be made under the Prior Plans. However, if any award previously granted under the Prior Plans, expires, terminates, is canceled, or is forfeited for any reason after the approval of the 2020 Plan, the shares subject to that award will be added to the 2020 Plan share pool so that they can be utilized for new grants under the 2020 Plan.

The 2020 Plan provides for the grant of incentive stock options (“ISOs”), nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit ("RSU") awards, and cash or other stock-based awards. ISOs may be granted only to the Company’s employees, including the Company’s officers, and the Company's employees, as well as officers and employees of its affiliates. All other awards may be granted to the Company’s employees, including the Company’s officers, the Company’s non-employee directors and consultants, and the employees and consultants of the Company’s affiliates.

The maximum number of shares that may be issued in respect of any awards under the 2020 Plan is the sum of: (i) 1,700,000 shares plus (ii) an annual increase on January 1, 2021 and each anniversary of such date thereafter through January 1, 2030, equal to the lesser of (A) 4% of the shares issued and outstanding on the last day of the immediately preceding fiscal year, or (B) such smaller number of shares as determined by the Board (collectively, the “Plan Limit”). The maximum aggregate number of shares that may be issued under the 2020 Plan is 8,000,000 over the ten-year term of the 2020 Plan.

As permitted by the 2020 Plan, the Company added 1,730,768 and 708,418 shares available for grant to the 2020 Plan on January 1, 2023 and January 1, 2022, respectively. As of June 30, 2023, 906,429 shares of common stock were available for grant under the 2020 Plan.

Stock Option Valuation

The following table presents, on a weighted average basis, the assumptions used in the Black-Scholes option-pricing model to determine the grant-date fair value of stock options granted to employees:

	June 30, 2023
Risk-free interest rate	3.64%
Expected term (in years)	6.23
Expected volatility	94%
Dividend yield	0.00%

Stock Options

The following table summarizes the Company’s stock option activity for the six months ended June 30, 2023 (amounts in millions, except for share, contractual term, and per share data):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (a) (in millions)
Outstanding as of December 31, 2022	3,071,528	$ 12.13	7.6	
Options granted	1,473,200	4.93		
Options forfeited/expired	(61,401)	11.53		
Outstanding as of June 30, 2023	4,483,327	$ 9.78	7.9	$ 0.1
Exercisable as of June 30, 2023	1,965,860	$ 13.08	6.5	$ —
Vested and expected to vest as of June 30, 2023	4,483,327	$ 9.78	7.9	$ 0.1

(a) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the fair value of the common stock for the options that were "in the money" at June 30, 2023.

Option Grants

During the six months ended June 30, 2023, the Company granted options to purchase 1,293,200 shares of common stock to employees under the 2020 Plan. The options have an exercise price equal to the closing stock price as of the grant date, and vest over four years, with 25% vesting on the first anniversary of the grant and the remainder vesting in equal monthly installments thereafter. The weighted-average grant date fair value of options granted under the 2020 Plan during the six months ended June 30, 2023 was $3.77.

At December 31, 2022, the aggregate intrinsic value of outstanding options granted under the 2020 Plan was $0.3 million. As noted in the table above, the aggregate intrinsic value of outstanding options at June 30, 2023 was $0.1 million.

As of June 30, 2023, total unrecognized compensation expense related to unvested stock options granted under the 2020 Plan was $12.8 million, which is expected to be recognized over a weighted average period of 2.38 years.

Inducement Stock Option Grant

During the six months ended June 30, 2023, the Company granted options to purchase 180,000 shares of common stock granted outside of the 2020 Plan. This grant was made pursuant to the Nasdaq inducement grant exception in accordance with Nasdaq listing rule 5635(c)(4). The options issued under this inducement grant have an exercise price equal to the closing stock price as of the grant date, and vest over four years, with 25% vesting on the first anniversary of the grant and the remainder vesting in equal monthly installments thereafter. The weighted-average grant date fair value of options granted under this inducement grant during the six months ended June 30, 2023 was $4.62.

As of June 30, 2023, total unrecognized compensation expense related to unvested inducement options granted was $0.8 million, which is expected to be recognized over a weighted average period of 3.61 years.

Restricted Stock Units

In January 2023, RSUs were granted under the 2020 Plan to the Company's employees in order to maintain retention of key employees. The value of an RSU award is based on the Company's stock price on the date of the grant. The shares underlying the RSUs are not issued until the RSUs vest.

Activity with respect to the Company's RSUs during the six months ended June 30, 2023 was as follows (in millions, except share, contractual term, and per share data):

	Number of Shares	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (a) (in millions)
Outstanding as of December 31, 2022	—	$	—	
Restricted stock units granted	650,000	4.94		
Restricted stock units forfeited	(4,000)	4.94		
Outstanding as of June 30, 2023	646,000	$ 4.94	2.1	$ 2.0
Unvested and expected to vest as of June 30, 2023	646,000	$ 4.94	2.1	$ 2.0

Restricted Stock Unit Grants

The RSUs vest annually over four years and have a weighted-average grant date fair value of $4.94 per unit.

As of June 30, 2023, total unrecognized compensation expense for RSUs was $2.9 million, which is expected to be recognized over a weighted-average period of 3.59 years.

Stock-Based Compensation

Stock-based compensation expense was classified in the condensed consolidated statements of operations as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Research and development	$ 864	$ 694	$ 1,608	$ 1,349
General and administrative	1,178	981	2,268	1,961
	$ 2,042	$ 1,675	$ 3,876	$ 3,310

8. Commitments and Contingencies

Intellectual Property Licenses

The Company is party to an exclusive License Agreement (the “WFUHS License”), dated November 30, 2016, as amended, with Wake Forest University Health Sciences (“WFUHS”) and an exclusive License Agreement (the “IU License”), dated November 30, 2016, as amended, with Indiana University (“IU”). Such agreements provide for a transferable, worldwide license to certain patent rights regarding technology used by the Company with respect to the development of CTI-1601. Both agreements continue from their effectve date through the last to expire of the applicable agreement's licensed patents unless earlier terminated by either party in accordance with their terms.

In partial consideration for the right and license granted under these agreements, the Company will pay each of WFUHS and IU a royalty of a low single digit percentage of net sales of licensed products depending on whether there is a valid patent covering such products. As additional consideration for these agreements, the Company is obligated to pay each of WFUHS and IU certain milestone payments of up to $2.6 million in the aggregate upon the achievement of certain developmental milestones, which commenced with the enrollment of the first patient in a Phase 1 clinical trial. The Company enrolled the first patient in its SAD trial on December 11, 2019 and paid WFUHS and IU less than $0.1 million. The Company will also pay each of WFUHS and IU sublicensing fees ranging from a high-single digit to a low double-digit percentage of sublicense consideration depending on the Company’s achievement of certain regulatory milestones as of the time of receipt of the sublicense consideration. The Company is also obligated to reimburse WFUHS and IU for patent-related expenses. In the event that the Company disputes the validity of any of the licensed patents, the royalty rate would be tripled during such dispute. The Company is also obligated to pay to IU a minimum annual royalty of less than $0.1 million per annum.

In the event that the Company is required to pay IU consideration, then the Company may deduct 20% of such IU consideration on a dollar-for-dollar basis from the consideration due to WFUHS. In the event that the Company is required to pay WFUHS consideration, then the Company may deduct 60% of such WFUHS consideration on a dollar-for-dollar basis from the consideration due to IU.

In October 2022, the Company initiated dosing of a phase 2 study. Pursuant to the terms of both the WFUHS License and the IU License, the company recognized milestone expense of $0.3 million within research and development expenses.

Both agreements continue from their effective date through the last to expire of the licensed patents unless earlier terminated by either party in accordance with their terms.

Leases

On November 5, 2018, the Company entered into an operating lease for office and lab space in Philadelphia, Pennsylvania, effective as of January 1, 2019, and expiring on December 31, 2020 with an option to extend the lease for two additional years. On August 4, 2020, the Company executed the first option to extend the lease for an additional year, expiring on December 31, 2021. On August 9, 2021, the Company executed the remaining option to extend the lease for an additional year, expiring on December 31, 2022. In January 2023, the Company executed an extension of this lease for an additional year, expiring on December 31, 2023. The Company has determined this lease extension qualifies as a short-term lease and have applied the accounting policy election to not record the related right-of-use asset and lease liabilities.

On August 8, 2019, the Company entered into an operating lease for office space in Bala Cynwyd, Pennsylvania, effective as of December 15, 2019, for a period of three years and six months with an option to extend the lease for three additional years. Due to required tenant improvements to be completed by the landlord, the Company did not take immediate possession of the leased property and the lease term commenced on February 15, 2020. On March 9, 2023, the Company executed the option to extend the lease for an additional three year term and to lease additional space. The lease term will commence on September 1, 2023 for both the extension of the current lease and the lease of additional operating space, no right of use asset or lease liability will be recorded until the lease commencement date.

On May 28, 2020, the Company acquired a non-cancellable operating lease for approximately 17,705 square feet of office space (the “Premises”). The lease expires on October 30, 2029. As part of the agreement, the Company is required to maintain a letter of credit, which upon signing was $1.3 million and is classified as restricted cash within the condensed consolidated financial statements. In addition to the base rent, the Company is also responsible for its share of operating expenses, electricity and real estate taxes, which costs are not included in the determination of the leases’ right-of-use assets or lease liabilities. The right-of-use asset is being amortized to other income/(expense) over the remaining lease term as a result of the sublease described below.

On October 27, 2020, the Company entered into a sublease agreement (the “Sublease”) with Massachusetts Municipal Association, Inc. (the “Subtenant”), whereby the Company sublet the entire Premises to the Subtenant. The initial term of the Sublease commenced on December 4, 2020 and continues until October 30, 2029. In connection with the Sublease, the Company evaluated the need for impairment under ASC 360 "*Impairment Testing: Long-Lived Assets Classified as Held and Used,"* and determined there was no impairment.

The Sublease provided for an initial annual base rent of $0.8 million, which increases annually up to a maximum annual base rent of $1.0 million. The Subtenant also is responsible for paying to the Company future increases in operating costs (commencing on January 1, 2022), future increases in annual tax costs (commencing July 1, 2021) and all utility costs (commencing March 1, 2021) attributable to the Premises during the term of the Sublease. As part of the Sublease, the subtenant deposited a letter of credit in the amount of $0.8 million to assure their performance under the sublease. If there are no uncured events of default under the sublease, the amount of this security deposit decreases over time to $0.4 million on the sixth anniversary of the Sublease. The Company records sublease income on this sublease on a straight-line basis as a component of other income/(expense).

Expense arising from operating leases was $0.1 million and $0.2 million during the three and six months ended June 30, 2023, respectively. Expense arising from operating leases was $0.1 million and $0.2 million during the three and six months ended June 30, 2022, respectively. For operating leases, the weighted-average remaining lease term for leases at June 30, 2023 and December 31, 2022 was 6.3 and 6.8 years, respectively. For operating leases, the weighted average discount rate for leases at June 30, 2023 and December 31, 2022 was 11.0%. The Company has not entered into any financing leases.

Maturities of lease liabilities due under these lease agreements as of June 30, 2023 are as follows:

(in thousands)	Operating Leases
Six months ending December 31, 2023	$ 540
Year ended December 31, 2024	1,065
Year ended December 31, 2025	1,083
Year ended December 31, 2026	1,101
Year ended December 31, 2027	1,118
Thereafter	2,095
Total lease payments	7,002
Less: imputed interest	(1,925)
Present value of lease liabilities	$ 5,077

Legal Proceedings

The Company is not currently a party to any litigation, nor is management aware of any pending or threatened litigation against the Company, that it believes would materially affect the Company's business, operating results, financial condition or cash flows.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q (the "Quarterly Report"), and the audited consolidated financial statements and notes thereto and management's discussion and analysis of financial condition and results of operations for the year ended December 31, 2022 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 14, 2023 (the "2022 Annual Report") and our Quarterly Report on Form 10-Q filed with the SEC on May 15, 2023. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks, uncertainties, and assumptions. These statements are based on our beliefs and expectations about future outcomes and are subject to risks and uncertainties that could cause our actual results to differ materially from anticipated results. We undertake no obligation to publicly update these forward-looking statements, whether as a result of new information, future events or otherwise. You should read the "Risk Factors" section included in our 2022 Annual Report, in addition to the "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" sections of this Quarterly Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biotechnology company focused on developing treatments for patients suffering from complex rare diseases using our novel cell penetrating peptide ("CPP") technology platform. Our lead product candidate, CTI-1601, is a subcutaneously administered, recombinant fusion protein intended to deliver frataxin ("FXN"), an essential protein, to the mitochondria of patients with Friedreich's ataxia ("FA"). FA is a rare, progressive, and fatal disease in which patients are unable to produce sufficient FXN due to a genetic abnormality. Currently, there are no treatment options that address the core deficit of FA, low levels of FXN. CTI-1601 represents the first potential therapy designed to increase FXN levels in patients with FA.

We believe that our CPP platform, which enables a therapeutic molecule to cross a cell membrane in order to reach intracellular targets, has the potential to enable the treatment of other rare and orphan diseases. We intend to use our proprietary platform to target additional orphan indications characterized by deficiencies in or alterations of intracellular content or activity.

Since our inception, we have devoted substantially all of our resources to developing CTI-1601, building our intellectual property portfolio, developing third-party manufacturing capabilities, business planning, raising capital, and providing general and administrative support for such operations.

CTI-1601 Program Update

We have completed two phase 1 clinical trials of CTI-1601 and the first cohort of a phase 2 trial in patients with FA:

- In May 2021, we reported positive top-line data from our Phase 1 FA program after completing dosing of the single ascending dose ("SAD") trial in December 2020 and of the multiple ascending dose ("MAD") trial in March 2021. Data from these trials demonstrate proof-of-concept by showing that daily subcutaneous injections of CTI-1601 for up to 13 days resulted in dose-dependent increases in FXN levels from baseline compared to placebo in all evaluated tissues (buccal cells, skin, and platelets). FXN levels achieved in peripheral tissues (buccal cells) following daily 50 mg and 100 mg subcutaneous injections of CTI-1601 were at or in excess of FXN levels that would be expected in phenotypically normal heterozygous carriers. There were no serious adverse events associated with either the MAD or SAD trials.
- In May 2023, we reported preliminary unblinded top-line data from the 25 mg cohort of our Phase 2 four-week, placebo-controlled, dose exploration trial of CTI-1601 in FA patients. Data from the cohort indicate CTI-1601 was generally well tolerated and showed increases in FXN levels from baseline compared to placebo in all evaluated tissues (skin and buccal cells) at day 14.

From May 2021 through July 2023, we have had ongoing interactions and discussions with the FDA regarding the clinical development of CTI-1601:

- In May 2021, the FDA placed a clinical hold on our CTI-1601 clinical program after we notified the agency of mortalities at the highest dose levels of a 26-week non-human ("NHP") toxicology study that was designed to support extended dosing of patients with CTI-1601. At the time the hold was placed, we had no interventional clinical trials with patients enrolling or enrolled.
- In February 2022, in response to the complete response we submitted to the FDA, the FDA stated that it was maintaining the clinical hold and that additional data were needed to resolve the clinical hold. We subsequently submitted a request to the FDA for a Type C meeting, which was granted and held in July 2022. We submitted a complete response incorporating additional information requested by the FDA at the meeting as well as information on the proposed study in August 2022.
- In September 2022, following the Type C meeting and the submission of the Company's complete response, the FDA allowed the 25 mg cohort of a Phase 2, four-week, placebo-controlled, dose exploration trial of CTI-1601 in FA patients discussed above to proceed. In connection with this decision, the FDA lifted its full clinical hold on the CTI-1601 clinical development program and imposed a partial clinical hold.
- In June 2023 we met with the Agency. Following that meeting, we submitted a complete response to the FDA's partial clinical hold that included unblinded safety, pharmacokinetic ("PK") and frataxin data from the Phase 2 trial's completed 25 mg cohort.
- Following the FDA's review of our complete response, in July 2023, the FDA cleared initiation of a second cohort of our four-week, placebo-controlled, Phase 2 dose exploration trial of CTI-1601 in patients with FA to proceed to a 50 mg cohort in which participants will be dosed daily for the first 14 days, and then every other day until day 28. This second cohort is designed to further characterize CTI-1601's safety, PK and pharmacodynamic profiles. We expect to report data from the Phase 2 trial's 50 mg cohort in the first half of 2024. In addition, the FDA cleared for initiation our open label extension ("OLE") trial in which participants will receive 25 mg of CTI-1601 daily. Participants who complete treatment in the first or second cohort of our Phase 2 dose exploration trial, or who previously participated in and completed a prior phase 1 clinical trial of CTI-1601, are eligible to screen for this OLE trial. The OLE trial is expected to begin in the first quarter of 2024 with interim data expected in the last quarter of 2024. Further dose escalation in the Phase 2 and OLE trials and the initiation of additional U.S. clinical trials evaluating CTI-1601 are contingent on FDA review of results from the Phase 2 trial's 50 mg cohort in accordance with a partial clinical hold.

CTI-1601 has been granted Orphan Drug (U.S. and Europe), Rare Pediatric Disease (U.S.), Fast Track (U.S.), and PRIME (Europe) designations for FA. We have also begun to engage with regulators and investigators outside the U.S. as we prepare to expand our clinical program to additional geographies. With approximately 75% of individuals with FA living outside the U.S., establishing global clinical trial capabilities is important for addressing the pressing unmet needs of the FA community.

Financing Activities

We have funded our operations to date primarily with proceeds from sales of common stock, proceeds from the sale of prefunded warrants for the purchase of common stock, the acquisition in 2020 of cash, cash equivalents, marketable securities and restricted cash upon the merger with Zafgen, Inc. ("Zafgen") and, prior to the 2020 merger with Zafgen, capital contributions from Chondrial Holdings, LLC.

In September 2022, we sold 25,558,750 shares of common stock in an underwritten offering for net proceeds of $75.2 million, after issuance costs.

In November 2022, we entered into a Sales Agreement (the "ATM Agreement") with an investment bank in connection with the establishment of an "at-the-market" offering program providing for the sale of up to an aggregate of $50.0 million of shares of our common stock from time to time through this investment bank as sales agent. To date, we have made no sales under this ATM agreement.

Financial Operations Overview

Revenue

To date, we have not generated any revenue from product sales, and do not expect to generate any revenue from the sale of products in the foreseeable future. If our development efforts result in clinical success and regulatory approval or collaboration agreements with third parties for our product candidates, we may generate revenue from those product candidates or collaborations.

Operating Expenses

The majority of our operating expenses since inception have consisted primarily of research and development and general and administrative costs.

Research and Development Expenses

Research and development expenses consist primarily of costs associated with our product research and development efforts and are expensed as incurred. Research and development expenses consist primarily of:

- third-party contract costs relating to research, formulation, manufacturing, non-clinical studies, and clinical trial activities;
- employee related costs, including cash compensation, benefits and stock-based compensation expenses for employees engaged in scientific research and development functions;
- external costs of outside consultants and vendors;
- payments made under our third-party licensing agreements;
- laboratory consumables; and
- allocated facility-related costs.

At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the clinical and commercial development of CTI-1601 or any other product candidates we may develop. We are also unable to predict when, if ever, material net cash inflows will commence from sales of our product candidates. The duration, costs, and timing of clinical trials and development of CTI-1601 or any other product candidates we develop will depend on a variety of factors, including:

- the scope, rate of progress and expense of clinical trials and other research and development activities;
- clinical trial results;
- uncertainties in clinical trial enrollment rate or design;
- significant and changing government regulation;
- the timing and receipt of any regulatory approvals;
- the influence of the FDA or other regulatory authorities on our clinical trial design and timing;
- our ability to expand or establish new manufacturing capabilities or making arrangements with third-party manufacturers and risks involved with development of manufacturing processes, FDA pre-approval inspection practices and successful completion of manufacturing batches for clinical development and other regulatory purposes;
- liquidity constraints, failure and instability of the U.S. and international banking systems, including possible impacts of a default by the U.S. government on its debt obligation, which could have broad macroeconomic effects that could, among other things, disrupt access to capital markets and deepen recessionary conditions;
- our ability to obtain and maintain patent and trade secret protection and regulatory exclusivity for our product candidates; and
- our ability to recruit and retain key research and development personnel.

A change in the outcome of any of these variables with respect to the development of a product candidate could significantly change the costs, timing and viability associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct additional non-clinical or clinical trials beyond those that we currently anticipate will be required for clinical development of a product candidate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on clinical development.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs, composed of cash compensation, related benefits and stock-based compensation, costs related to our executive, finance, information technology, and costs related to other administrative functions. General and administrative expenses also include insurance expenses and professional fees for auditing, tax, and legal services, including legal expenses to pursue patent protection for our intellectual property. We expect that our general and administrative expenses will increase in the foreseeable future as we hire additional employees to implement, improve and scale our operational, financial, commercial and management systems.

Critical Accounting Policies and Significant Judgments and Estimates

Our condensed consolidated financial statements are prepared in accordance with GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amount of assets, liabilities, costs and expenses, and related disclosures. We believe that the estimates and assumptions involved in the accounting policies described below may have the greatest potential impact on our consolidated financial statements and, therefore, consider these to be our critical accounting policies. We evaluate these estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions and conditions.

Research and Development Expense

Costs for certain research and development activities, such as manufacturing, non-clinical studies and clinical trials are generally recognized based on the evaluation of the progress of completion of specific tasks using information and data provided by our vendors and collaborators, and accordingly, are considered an area of significant judgement and management's review of manufacturing, nonclinical and clinical expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel and outside vendors to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. We work with vendors and suppliers to ensure that our estimates of our research and development expenses are reasonable. We expect to increase our investment in research and development in order to advance CTI-1601 through additional clinical trials. As a result, we expect that our research and development expenses will increase in the foreseeable future as we pursue clinical development of CTI-1601 and/or any other product candidates we develop.

Stock Compensation Expense

We measure all stock-based awards granted to employees and directors based on the fair value on the date of grant using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model requires the use of highly subjective assumptions which determine the fair value of stock-based awards. The assumptions used in our option-pricing model represent management’s best estimates. These estimates are complex, involve a number of variables, uncertainties and assumptions and the application of management’s judgment, and thus are inherently subjective. If factors change and different assumptions are used, our stock-based compensation expense could be materially different in the future.

Prior to May 28, 2020, we were a private company and lacked company-specific historical and implied volatility information for our common stock. Prior to January 1, 2023, the Company estimated its expected common stock price volatility solely based on the historical volatility of publicly traded peer companies with comparable characteristics including enterprise value, risk profiles and position within the industry. Beginning on January 1, 2023, the Company began blending it historical data starting in June 2020 (following its merger with Zafgen in 2020) with its historical peer group. We regularly evaluate our peer group to assess changes in circumstances where identified companies may no longer be similar to us, in which case, more suitable companies whose share prices are

publicly available would be utilized in the calculation. We expect to continue to do so until we have full historical data regarding the volatility of our own traded stock price.

The expected term of our stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The expected dividend yield considers the fact that we have never paid cash dividends on common stock and do not expect to pay any cash dividends in the foreseeable future.

Compensation expense of those awards is recognized over the requisite service period, which is generally the vesting period of the respective award. Typically, we issue awards with only service-based vesting conditions and record the expense for these awards using the straight-line method. We account for forfeitures as they occur.

We classify stock-based compensation expense in our condensed consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Results of Operations

Comparison of three months ended June 30, 2023 and 2022

The following table summarizes our results of operations for the three months ended June 30, 2023 and 2022:

	Three Months Ended June 30,		
	2023	2022	Increase (Decrease)
	(in thousands)		
Statement of Operations Data:			
Operating expenses:			
Research and development	$ 5,875	$ 5,644	$ 231
General and administrative	3,745	3,043	702
Total operating expenses	9,620	8,687	933
Loss from operations	(9,620)	(8,687)	(933)
Other income (expense), net	1,254	20	1,234
Net loss	$ (8,366)	$ (8,667)	$ 301

Research and development expenses

Research and development expenses for the three months ended June 30, 2023 increased $0.2 million compared to the three months ended June 30, 2022. The increase in research and development expenses was primarily driven by an increase of $0.5 million in test method development and optimization, an increase of $0.4 million in personnel related costs, an increase of $0.2 million in stock-based compensation expense associated with stock option grants made in 2022 and 2023, partially offset by a decrease of $1.1 million in clinical supply manufacturing costs.

General and administrative expenses

General and administrative expenses for the three months ended June 30, 2023 increased $0.7 million compared to the three months ended June 30, 2022. The increase in general and administrative expense was primarily driven by an increase of $0.3 million of professional fees primarily related to increased legal expense, an increase of $0.2 million in stock-based compensation expense associated with stock option grants made in 2022 and 2023 and an increase of $0.2 million in personnel related costs related to increases in headcount.

Other income (expense), net

Other income (expense), net was $1.3 million of income in the three months ended June 30, 2023 compared to less than $0.1 million in the three months ended June 30, 2022. The increase primarily relates to interest income on a higher investment base and higher interest rates on that base during the period.

Results of Operations

Comparison of six months ended June 30, 2023 and 2022

The following table summarizes our results of operations for the six months ended June 30, 2023 and 2022:

	Six Months Ended June 30,		
	2023	2022	Increase (Decrease)
	(in thousands)		
Statement of Operations Data:			
Operating expenses:			
Research and development	$ 10,437	$ 11,450	$ (1,013)
General and administrative	6,820	6,124	696
Total operating expenses	17,257	17,574	(317)
Loss from operations	(17,257)	(17,574)	317
Other income (expense), net	2,365	(36)	2,401
Net loss	$ (14,892)	$ (17,610)	$ 2,718

Research and development expenses

Research and development expenses for the six months ended June 30, 2023 decreased $1.0 million compared to the six months ended June 30, 2022. The decrease in research and development expenses was primarily driven by a decrease of $1.5 million in clinical supply manufacturing costs, a decrease in assay development costs of $0.2 million partially offset by an increase of $0.5 million in personnel related costs, an increase of $0.3 million in stock-based compensation expense associated with stock option grants made in 2022 and 2023.

General and administrative expenses

General and administrative expenses for the six months ended June 30, 2023 increased $0.7 million compared to the six months ended June 30, 2022. The increase in general and administrative expense was primarily driven by an increase of $0.3 million in stock-based compensation expense associated with stock option grants made in 2022 and 2023, an increase of $0.3 million of professional fees primarily related to increased legal expense, and an increase of $0.2 million in personnel related costs related to increases in headcount.

Other income (expense), net

Other income (expense), net was $2.4 million of income in the six months ended June 30, 2023 compared to less than $0.1 million of net expense in the six months ended June 30, 2022. The increase primarily relates to interest income on a higher investment base and higher interest rates on that base during the period.

Liquidity and Capital Resources

Since our inception, we have not generated any revenue from any sources, including from product sales, and have incurred significant operating losses and negative cash flows from our operations. We have devoted substantially all of our resources to developing CTI-1601, building our intellectual property portfolio, developing third-party manufacturing capabilities, business planning, capital raising, and providing general and administrative support for such operations.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented below:

	Six Months Ended June 30,	
	2023	2022
	(in thousands)	
Net cash used in operating activities	$ (14,916)	$ (15,019)
Net cash provided by (used in) investing activities	82,412	(35,342)
Net cash provided by financing activities	—	—
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 67,496	$ (50,361)

Net cash used in operating activities

During the six months ended June 30, 2023, operating activities used $14.9 million of cash, resulting from our net loss of $14.9 million, adjusted for noncash expenses of $3.3 million and changes in our operating assets and liabilities utilizing cash of $3.4 million. Our net loss was primarily attributed to research and development activities related to our CTI-1601 program and our general and administrative expenses as described above. Noncash expenses primarily relate to stock-based compensation expenses. The change in operating assets and liabilities was primarily due to a decrease in accrued expenses and offset by an increase in accounts payable.

During the six months ended June 30, 2022, operating activities used $15.0 million of cash, resulting from our net loss of $17.6 million, adjusted for noncash expenses of $3.5 million. Our net loss was primarily attributed to research and development activities related to our CTI-1601 program and our general and administrative expenses as described above. Noncash expenses are primarily stock-based compensation expense. The change in operating assets and liabilities was primarily due to decreases in prepaid expenses and accounts payable.

Net cash provided by (used in) investing activities

During the six months ended June 30, 2023, investing activities provided $82.4 million of cash, including $92.3 million from maturities of marketable securities and partially offset by $9.8 million in purchases of marketable securities.

During the six months ended June 30, 2022, investing activities used $35.3 million of cash, including $35.2 million in purchases of new marketable securities and $0.1 million in purchases of property and equipment.

Net cash provided by financing activities

During the six months ended June 30, 2023 and 2022 there were no financing activities.

Operating Capital Requirements

We have not yet commercialized any products and do not expect to generate revenue from the commercial sale of any products for several years, if at all.

We have to date incurred net losses. We incurred net losses of approximately $14.9 million and $17.6 million for the six months ended June 30, 2023 and 2022, respectively. As of June 30, 2023, we had an accumulated deficit of $166.5 million and cash, cash equivalents and marketable securities of $104.2 million, excluding restricted cash of $1.3 million.

Losses have resulted principally from costs incurred in connection with research and development activities, and general and administrative costs associated with the development of CTI-1601 and our operations. We expect to incur significant expenses and operating losses for the foreseeable future as we expect to continue to incur expenses in connection with our ongoing activities, if and as we:

- continue to advance the development of CTI-1601 through additional clinical trials;
- seek to identify and advance development of additional product candidates into clinical development and identify additional indications for our product candidates;
- seek to obtain regulatory approvals for CTI-1601 and other potential product candidates;
- identify, acquire or in-license other product candidates and technologies;
- maintain, leverage and expand our intellectual property portfolio; and
- expand our operational, financial, commercial and management systems and personnel, including personnel to support our clinical development and future commercialization efforts and our operations as a public company.

We believe that based on our current operating plan our cash, cash equivalents and marketable securities will be able to fund operating expenses and capital expenditure requirements for at least the next twelve months from the filing of these financial statements with the SEC. If we encounter unexpected delays in our clinical trials or if there are other unanticipated changes to our operating plan from our current assumptions that negatively impact our operations, we may reduce expenditures in order to further extend our existing cash resources. Until we can generate substantial revenue, if ever, we expect to seek additional funding through a combination of public or private equity

offerings, debt financings, collaborations, strategic alliances and licensing arrangements or other sources. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, minimum cash balances, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates.

There can be no assurance that we will be able to raise sufficient additional capital on acceptable terms, if at all. If such additional financing is not available on satisfactory terms, or is not available in sufficient amounts, or we do not have sufficient authorized shares, we may be required to delay, limit, or eliminate the development of business opportunities and our ability to achieve our business objectives, our competitiveness, and our business, financial condition, and results of operations will be materially adversely affected. We could also be required to seek funds through arrangements with collaborative partners, strategic alliances or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. In addition, geopolitical tensions, volatility of capital markets, and other adverse macroeconomic events, including those due to inflationary pressures, rising interest rates, bank instability and the ability of the U.S. government to manage federal debt limits, as well as the potential impact of health crises on the global financial markets may reduce our ability to access capital, which could negatively affect our liquidity and ability to continue as a going concern.

If we are unable to obtain sufficient funding when needed and/or on acceptable terms, we may be required to significantly curtail, delay or discontinue one or more of our research and development programs, the manufacture of clinical and commercial supplies, product portfolio expansion and/or pre commercialization efforts, which could adversely affect our business prospects, or we may be unable to continue operations. Certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates.

Off-Balance Sheet Arrangements

During the periods presented we did not have, and we currently do not have, any off-balance sheet arrangements, as defined under applicable SEC rules, such as relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our balance sheets.

Recently Issued Accounting Pronouncements

Please read Note 2 to our condensed consolidated financial statements included in Part I of Item 1 of this Quarterly Report for a description of recent accounting pronouncements applicable to our business, if any.

Other Company Information

None.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We are a "smaller reporting company" as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and are not required to provide the information under this item.

Item 4. Controls and Procedures

We maintain “disclosure controls and procedures,” as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, to allow timely decisions regarding required disclosure.

The design of disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

With respect to the quarter ended June 30, 2023, under the supervision and with the participation of our management, we conducted an evaluation of the effectiveness of the design and operations of our disclosure controls and procedures. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective.

Management does not expect that our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control systems are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in a cost-effective control system, no evaluation of internal control over financial reporting can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been or will be detected.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended June 30, 2023 which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we are subject to claims in legal proceedings arising in the normal course of business. To our knowledge, during the three months ended June 30, 2023, there were no, and as of the date of this Quarterly Report, there are no, threatened or pending legal actions that could reasonably be expected to have a material adverse effect on our business, financial condition, results of operations or cash flows.

Item 1A. Risk Factors

You should carefully consider the risk factors described in our 2022 Annual Report under the caption "Item 1A. Risk Factors." Except as set forth below, there have been no material changes in our risk factors disclosed in our 2022 Annual Report. The risks described in our 2022 Annual Report are not the only risks facing our company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition or future results.

Risks Related to Our Product Development and Regulatory Approvals

Further dose escalation in our Phase 2 and OLE trials and the initiation of additional U.S. clinical trials evaluating CTI-1601 will be contingent on the FDA allowing such trials to proceed following review of data from the 50 mg cohort of our Phase 2 clinical trial; if the FDA does not allow additional trials to proceed, we may be unable to complete our CTI-1601 clinical trials without delays and our business may be adversely affected and our stock price may decline.

In July 2023, the FDA cleared our four-week, placebo-controlled, Phase 2 dose exploration trial of CTI-1601 in patients with FA to proceed to a 50 mg cohort in which participants will be dosed daily for the first 14 days, and then every other day until day 28. Additionally, the FDA cleared for initiation our OLE trial in which participants will receive 25 mg of CTI-1601 daily. Further dose escalation in the Phase 2 and OLE trials and the initiation of additional U.S. clinical trials evaluating CTI-1601 are contingent on FDA review of results from any ongoing clinical trials in accordance with a partial clinical hold. If, following completion of our Phase 2 trial's 50 mg cohort, we are unable to reach agreement with the FDA to conduct additional clinical trials, we may be unable to complete our CTI-1601 clinical trials without delays in our clinical development plans and anticipated data milestones and additional clinical development costs, any of which could impair our ability, cost or timeline to obtain U.S. regulatory approval for CTI-1601.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

The exhibits filed as part of this Quarterly Report are set forth on the Exhibit Index, which is incorporated herein by reference.

EXHIBIT INDEX

Exhibit No.	Description
10.1*	Employment Agreement dated May 23, 2023, by and between the Company and Russell Clayton
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document- the instance document does not appear in the Interactive Data File because its XBRL tag re embedded within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Link Document.
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

* Filed herewith.

** Furnished herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

LARIMAR THERAPEUTICS, INC.

Date: August 10, 2023

By: /s/ Carole S. Ben-Maimon, M.D.

Carole S. Ben-Maimon, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 10, 2023

By: /s/ Michael Celano

Michael Celano
Chief Financial Officer
(Principal Financial and Accounting Officer)

EMPLOYMENT AGREEMENT

This Employment Agreement (the "**Agreement**") is made on May 23, 2023 by and between LARIMAR THERAPEUTICS, INC. (the "**Company**") and RUSSELL G. CLAYTON SR., D.O. (the "**Executive**").

Introduction

The Company desires to retain the services of the Executive pursuant to the terms and conditions set forth herein and the Executive wishes to be employed by the Company on such terms and conditions. The Executive will be a key employee of the Company, with significant access to information concerning the Company and its business. The disclosure or misuse of such information or the engaging in competitive activities would cause substantial harm to the Company.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. Term. The Company agrees to employ Executive, and Executive accepts employment with the Company, on the terms and subject to the conditions of this Agreement. Executive's period of employment with the Company will commence on July 17, 2023 or such other date agreed by the parties (the "**Effective Date**") and will continue until terminated in accordance with this Agreement.

2. Duties. The Executive will serve as the Chief Medical Officer of the Company and shall have such duties of an executive nature as the Board of Directors of the Company (the "**Board**") shall determine from time to time. The Executive will report to the Company's Chief Executive Officer.

3. Full Time; Best Efforts. The Executive shall devote Executive' s full business time and best efforts to the performance of Executive' s duties hereunder and to the promotion of the business and affairs of the Company. The Executive shall not engage in any other commercial activity; provided however, that the Executive may, with the approval of the Chief Executive Officer, serve on a clinical or scientific advisory board or accept an appointment on a board of directors of a company, so long as such service does not represent a potential conflict of interest or interfere with the performance of the Executive' s duties and responsibilities hereunder. Similarly, the Executive may engage in charitable or civic endeavors so long as they do not interfere with the performance of the Executive' s duties and responsibilities hereunder. The Executive shall not engage in any other activity which could reasonably be expected to interfere with the performance of the Executive's duties, services and responsibilities hereunder.

4. Compensation and Benefits. During the Executive's employment with the Company under this Agreement, the Executive shall be entitled to compensation and benefits as follows:

(a) Base Salary. The Executive will receive a salary at the rate of $425,000 annually, payable in equal increments not less often than monthly in arrears. The Executive's rate of base

salary, as in effect from time to time, (the "**Base Salary**") will be reviewed at least annually by the Compensation Committee of the Board (the "**Committee**") and may not be decreased, except in

connection with a proportionate reduction of the salaries of all the Company's other executive officers.

(b) Bonus. For each calendar year ending during his employment, the Executive will have the opportunity to earn an annual bonus (the "**Bonus**") with a target amount not less than 40% of the Base Salary actually earned by the Executive in the applicable year. The actual Bonus payable to the Executive, if any, may be more or less than the target amount and will be determined by the Committee, in its sole discretion, based on the achievement of corporate and/or personal objectives established by the Committee. Except as otherwise provided herein or determined by the Committee, payment of any otherwise earned Bonus will be conditioned on Executive's continued service through the date that annual bonuses are paid to the Company's executive officers generally with respect to the applicable year.

(c) Initial Equity Award. As an inducement for the Executive to enter into this Agreement and accept employment with the Company, on the first trading day of first calendar month commencing after the Effective Date (the "**Grant Date**") and provided the Executive is then in service with the Company, the Company will grant to the Executive a stock option (the "**Initial Award**") in respect of 180,000 shares of the Company's common stock. The Initial Award will have an exercise price equal to the closing price of the Company's common stock on the Grant Date and will vest as follows: (i) 25% of the Initial Award will vest on the first anniversary of the Grant Date, and (ii) the remaining 75% of the Initial Award will in equal monthly installments (on the last day of each of the 36 calendar months commencing after the first anniversary of the Grant Date), subject in each case to the Executive's continued service to the Company through the applicable vesting date. The Initial Award will be subject to additional terms and conditions specified by the Committee, in its discretion, and will be memorialized in a separate award agreement in form and substance acceptable to the Company.

(d) Benefits. The Executive shall be entitled to participate in Company benefit plans that are generally available to the Company' s executive employees in accordance with and subject to the terms and conditions of such plans, as in effect from time to time.

(e) Vacation. The Executive will be entitled to paid time off in accordance with the Company's policies, as in effect from time to time.

(f) Expenses. The Executive will be entitled to reimbursement of all reasonable expenses incurred in the ordinary course of business on behalf of the Company in accordance with Company expense reimbursement policies.

(g) Withholding. The Company may withhold from compensation payable to the Executive all applicable federal, state and local withholding taxes.

5. Restrictive Covenant Agreement. In consideration of the good and valuable consideration received hereunder, the Executive will promptly execute the Confidentiality,

Intellectual Property Assignment and Restrictive Covenant Agreement attached hereto as Appendix A (the "**Restrictive Covenant Agreement**").

6. Termination.

(a) General. The Executive's employment with the Company may be terminated by the Company at any time, for any reason. The Executive's employment with the Company may also be terminated by the Executive for Good Reason or, after at least 30 days prior written notice thereof from the Executive to the Company, without Good Reason (provided that upon notice by the Executive of a resignation without Good Reason, the Company may without any liability accept such resignation with an earlier effective date than proposed by the Executive).

(b) Definitions. As used herein, the following terms shall have the following meanings:

"**Cause**" shall mean: (a) a good faith finding by the Company's Board (i) of a willful failure of the Executive to perform his reasonably assigned duties for the Company, which failure is not cured within ten days after written notice thereof, unless the Board determines in good faith such failure is not curable, or (ii) that the Executive has engaged in a material act of dishonesty, gross negligence or material misconduct; (b) the conviction of the Executive of, or the entry of a pleading of guilty by the Executive to, a felony; or (c) a breach by the Executive of any duty owed to or any agreement with the Company, which breach is not cured within ten days after written notice thereof, unless the Board determines in good faith such breach is not curable. For avoidance of doubt, any termination of the Executive's employment due to a Disability (as defined below) will not be deemed a termination "without Cause."

"**Change in Control**" means a "change in control event," as that term is used in Treas. Reg. § 1.409A-3(i)(5)(i).

"**Disability**" means Executive's inability to substantially perform his duties to the Company as a result of incapacity by reason of any medically determinable physical or mental impairment that can be expected to result in death or to last for a period of at least 12 months.

"**Good Reason**" for resignation shall exist upon, without the Executive's written consent: (a) a change by the Company in the location at which the Executive performs his principal duties for the Company of more than 25 miles from the location at which the Executive was performing his principal duties for the Company prior to such change; (b) a reduction of the Executive's Base Salary (other than a reduction permitted by Section 4(a)); (c) a reduction of the Executive's target Bonus opportunity below that specified in Section 4(b); or (d) a material adverse change in the Executive's title, authority or duties; provided that no such event or condition in clauses (a) through (d) shall constitute Good Reason unless (x) the Executive gives the Company a written notice of termination not more than 30 days after the initial existence of the condition, (y) the grounds for termination (if susceptible to correction) are not corrected by the Company within 30 days of its receipt of such notice, and (z) the Executive's termination occurs within 60 days following the Company's receipt of such notice.

(c) Effects of Termination. If the Executive's employment with the Company ceases for any reason, then the Executive's rights in respect of outstanding equity awards will be determined in accordance with terms of the applicable award agreements and the Company will pay to the Executive any Base Salary that had been earned but not yet paid, and any expenses subject to

reimbursement under Section 4(f) that had been incurred but not yet reimbursed, in each case prior to the date of termination (collectively, the "**Accrued Rights**"). All compensation and benefits will cease at the time of such cessation of employment and, except as otherwise provided by COBRA or as expressly provided herein, the Company will have no further liability or obligation by reason of such cessation. Contemporaneous with any cessation of the Executive's employment, unless otherwise requested by the Board, the Executive will resign from all officer and director positions with the Company and its affiliates and execute such documents as may be requested by the Company to confirm that resignation.

(d) Involuntary Termination. If the Executive' s employment ceases due to a termination by the Company without Cause or a resignation by the Executive with Good Reason, then in addition to the Accrued Rights and subject to Section 6(f) below, Executive will be entitled to receive:

(i) payment of any Bonus otherwise earned and payable (but for the cessation of the Executive's employment), but not yet paid, in respect of the calendar year immediately preceding such cessation (the "**Prior Year Bonus**");

(ii)monthly severance payments for a period of nine months, with each payment equal to one-twelfth the Base Salary (as in effect immediately prior to such cessation or, if the cessation is a resignation for the Good Reason described in clause (b) of the definition thereof, as in effect immediately prior to such Good Reason); and

(iii)waiver or reimbursement of the applicable premium otherwise payable or paid for COBRA continuation coverage for Executive (and, to the extent covered immediately prior to the date of such cessation, his eligible dependents) for a period equal to nine months.

(e) Involuntary Termination Proximate to a Change in Control. Notwithstanding the foregoing, if a cessation of employment described in this Section 6(d) occurs during the one year period immediately following a Change in Control, then

(i) Section 6(d)(ii) will be replaced with the following: "monthly severance payments for a period of 12 months, with each payment equal to one-twelfth the sum of (A) the Base Salary (as in effect immediately prior to such cessation or, if the cessation is a resignation for the Good Reason described in clause (b) of the definition thereof, as in effect immediately prior to such Good Reason), plus (B) the target Bonus opportunity for the year of the cessation (as in effect immediately prior to such cessation or, if the cessation is a resignation for the Good Reason described in clause (c) of the definition thereof, as in effect immediately prior to such Good Reason);" and

(ii)the reference in Section 6(d)(iii) to "nine months" will be replaced with "12 months."

(f) Severance Benefits Conditioned on Release. The payments and benefits described in Section 6(d)(i) – (iii) (as modified by Section 6(e), if applicable)(the "**Severance Benefits**") are in lieu of, and not in addition to, any other severance arrangement maintained by the Company. The Severance Benefits are conditioned on Executive's execution and delivery to the Company of a general release of claims against the Company and its affiliates in such form as the Company may

prescribe (the "Release") and on such Release becoming irrevocable within 30 days following his cessation of employment. The Prior Year Bonus, if any, will be paid on the date that annual bonuses are paid to other executive officers generally with respect to the applicable year or, if later, within 15 days after the Release has become irrevocable. Subject to Section 17 below, the Severance Benefits described in Section 6(d)(ii) and (iii) (as modified by Section 6(e), if applicable) will begin to be paid or provided (x) 15 days after the Release has become irrevocable, if the 45-day period following the cessation of employment does not straddle two calendar years; or (y) the later of 15 days after the Release has become irrevocable or the first regularly scheduled payroll date in the calendar year following the cessation of employment, if the 45-day period following such cessation straddles two calendar years.

(g) Death or Disability. If the Executive's employment ceases due to the Executive's death or Disability, then in addition to the Accrued Rights, the Executive (or his estate or personal representative, as applicable) will be entitled to receive any otherwise unpaid Prior Year Bonus. Such Prior Year Bonus, if any, will be paid on the same date that annual bonuses are paid to other executive officers generally with respect to the applicable year.

7. Notices. All notices, demands or other communications hereunder shall be in writing and shall be deemed to have been duly given if delivered in person, by e-mail or fax, by United States mail, certified or registered with return receipt requested, or by a nationally recognized overnight courier service, or otherwise actually delivered: (a) if to the Executive, at the most recent address contained in the Company's personnel files; (b) if to the Company, to the attention of its Legal Department at the address of its principal executive office; or (c) or at such other address as may have been furnished by such person in writing to the other party. Any such notice, demand or communication shall be deemed given on the date given, if delivered in person, e-mailed or faxed, on the date received, if given by registered or certified mail, return receipt requested or by overnight delivery service, or three days after the date mailed, if otherwise given by first class mail, postage prepaid.

8. Governing Law. This Agreement shall be governed by and construed in accordance with the internal laws of the State of Delaware, without regard to its choice of law provisions.

9. Arbitration. In the event of any dispute under the provisions of this Agreement or otherwise regarding the Executive's employment or compensation (other than a dispute in which the primary relief sought is an injunction or other equitable remedy, such as an action to enforce compliance with the Restrictive Covenant Agreement), the parties shall be required to have the dispute, controversy or claim settled by arbitration in Philadelphia, Pennsylvania in accordance with the National Rules for the Resolution of Employment Disputes then in effect of the American Arbitration Association ("**AAA**"), by one arbitrator mutually agreed upon by the parties (or, if no agreement can be reached within 30 days after names of potential arbitrators have been proposed by the AAA, then by one arbitrator having relevant experience who is

chosen by the AAA). Any award or finding will be confidential. The arbitrator may not award attorneys' fees to either party unless a statute or contract at issue specifically authorizes such an award. Any award entered by the arbitrators will be final, binding and non-appealable and judgment may be entered thereon by either party in accordance with applicable law in any court of competent jurisdiction. This arbitration provision will be specifically enforceable. Each party

will be responsible for its own expenses relating to the conduct of the arbitration (including reasonable attorneys' fees and expenses) and will share equally the fees of the arbitrator.

10. Amendments. This Agreement may be amended or modified only by a written instrument signed by a duly authorized officer of the Company and the Executive.

11. No Waivers. No waiver of this Agreement or any provision hereof shall be binding upon the party against whom enforcement of such waiver is sought unless it is made in writing and signed by or on behalf of such party. The waiver of a breach of any provision of this Agreement shall not be construed as a waiver or a continuing waiver of the same or any subsequent breach of any provision of this Agreement. No delay or omission in exercising any right under this Agreement shall operate as a waiver of that or any other right.

12. Binding Effect. This Agreement shall be binding on and inure to the benefit of the parties hereto and their respective heirs, executors and administrators, successors and assigns, except that the rights and obligations of the Executive hereunder are personal and may not be assigned without the Company' s prior written consent. Any assignment of this Agreement by the Company shall not be considered a termination of the Executive's employment.

13. Entire Agreement. This Agreement, together with the Restrictive Covenant Agreement, constitutes the final and entire agreement of the parties with respect to the matters covered hereby and replaces and supersedes all other agreements and understandings relating hereto and to the Executive's employment.

14. Counterparts. This Agreement may be executed in any number of counterparts, including counterpart signature pages or counterpart facsimile signature pages, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

15. No Conflicting Agreements. The Executive represents and warrants that he is not a party to or otherwise bound by any agreement or restriction that could conflict with, or be violated by, the performance of his duties to the Company or his obligations under this Agreement. Executive will not use or misappropriate any intellectual property, trade secrets or confidential information belonging to any third party.

16. Interpretation. The captions of the sections of this Agreement are for convenience of reference only and in no way define, limit or affect the scope or substance of any section of this Agreement. The parties have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises under any provision of this Agreement, this Agreement shall be construed as if drafted jointly by the parties

thereto, and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of authoring any of the provisions of this Agreement.

17. Section 409A.

(a) The parties intend for this Agreement to comply with or be exempt from Section 409A of the Internal Revenue Code of 1986, as amended (the "**Code**"), and all provisions of this Agreement will be interpreted and applied accordingly. Nonetheless, the Company does not guaranty the tax treatment of any compensation payable to the Executive.

(b) If the cessation of employment giving rise to the payments described in Section 6(d) (as modified by Section 6(e), if applicable) is not a "Separation from Service" within the meaning of Treas. Reg. § 1.409A-1(h)(1) (or any successor provision), then the amounts otherwise payable pursuant to that section will instead be deferred without interest and will not be paid until the Executive experiences a Separation from Service. In addition, to the extent compliance with the requirements of Treas. Reg. § 1.409A-3(i)(2) (or any successor provision) is necessary to avoid the application of an additional tax under Section 409A of the Code to payments due to the Executive upon or following his Separation from Service, then notwithstanding any other provision of this Agreement (or any otherwise applicable plan, policy, agreement or arrangement), any such payments that are otherwise due within six months following the Executive's Separation from Service (taking into account the preceding sentence of this paragraph) will be deferred without interest and paid to Executive in a lump sum immediately following that six-month period. This paragraph should not be construed to prevent the application of Treas. Reg. § 1.409A-1(b)(9)(iii)(or any successor provision) to amounts payable hereunder. For purposes of the application of Treas. Reg. § 1.409A-1(b)(4)(or any successor provision), each payment in a series of payments will be deemed a separate payment.

(c) Notwithstanding anything in this Agreement to the contrary, to the extent an expense, reimbursement or in-kind benefit provided to the Executive pursuant to this Agreement or otherwise constitutes a "deferral of compensation" within the meaning of Section 409A of the Code (a) the amount of expenses eligible for reimbursement or in-kind benefits provided to the Executive during any calendar year will not affect the amount of expenses eligible for reimbursement or in-kind benefits provided to the Executive in any other calendar year, (b) the reimbursements for expenses for which the Executive is entitled to be reimbursed shall be made on or before the last day of the calendar year following the calendar year in which the applicable expense is incurred, and (c) the right to payment or reimbursement or in-kind benefits hereunder may not be liquidated or exchanged for any other benefit.

18. Section 280G. Notwithstanding any other provision of this Agreement or the terms of any other agreement, award or plan, if any payment to or for the benefit of the Executive, whether paid or payable pursuant to the terms of this Agreement or otherwise (each, a "**Payment**," and collectively, the "**Total Payments**"), would be subject (in whole or in part) to the excise tax imposed by Section 4999 of the Code (the "**Excise Tax**"), then the Total Payments shall be reduced to the minimum extent necessary to avoid the imposition of the Excise Tax on the Total Payments, but only if (i) the net amount of such Total Payments, as so reduced, is greater than or equal to (ii) the net amount of such Total Payments without such reduction (in

each case, after subtracting the expected federal, state and local taxes on such Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such Total Payments). The reduction of the Total Payments contemplated in this paragraph will be implemented by determining the Parachute Payment Ratio (as defined below), as determined in good faith by the Company, for each Payment and then reducing the Total Payments in order

beginning with the Payment with the highest Parachute Payment Ratio. For Payments with the same Parachute Payment Ratio, such Payments will be reduced based on the time of payment of such Payments, with the latest Payments reduced first. For Payments with the same Parachute Ratio and the same time of payment, each such Payment will be reduced proportionately. For purposes hereof, the term "**Parachute Payment Ratio**" shall mean a fraction, (x) the numerator of which is the value of the applicable Total Payment (as calculated for purposes of Section 280G of the Code), and (y) the denominator of which is the intrinsic (i.e., economic) value of such Total Payment.

19. CARES Act Limitation. Notwithstanding anything to the contrary in this Agreement or otherwise, to the extent required to enable the Company to qualify for a loan, loan guarantee or other form of financial assistance with the Secretary of the Treasury or other governmental entity under the Coronavirus Aid, Relief, and Economic Security Act (as may be amended or modified, the "**CARES Act**"), the Executive's rights to compensation from the Company, whether under this Agreement or otherwise, will be limited to the maximum amounts permitted under Section 4004 of the CARES Act.

20. Company Policies. The Executive will be subject to all policies of the Company in effect from time to time, including (without limitation) policies regarding ethics, personal conduct, stock ownership, securities trading, clawback and hedging and pledging of securities.

This Agreement has been executed and delivered on the date first above written.

LARIMAR THERAPEUTICS, INC.

By: /s/ Carole Ben-Maimon

Name: Carole Ben-Maimon

Title: President and CEO

EXECUTIVE

/s/ Russell Clayton

Russell G. Clayton Sr., D.O.

(***SIGNATURE PAGE TO EMPLOYMENT AGREEMENT***)

Appendix A

LARIMAR THERAPEUTICS, INC.

Confidentiality, Intellectual Property Assignment and Restrictive Covenant Agreement (the "Agreement")

In consideration and as a condition of my service relationship, whether as an employee, consultant, advisor or otherwise (collectively, "Service Relationship") with Larimar Therapeutics, Inc. or any of its current or future parents, subsidiaries or affiliates (collectively, the "Company"), I agree as follows:

1. Confidential Information.

(a) I agree that all information, whether or not in writing, concerning the Company's business, technology, business relationships or financial affairs which the Company has not released to the general public (collectively, "Confidential Information") is and will be the exclusive property of the Company. Confidential Information also includes information received in confidence by the Company from its customers or suppliers or other third parties. Confidential Information may include, without limitation, information on finance, structure, business plans, employee performance, staffing, compensation of others, research and development, operations, manufacturing and marketing, strategies, customers, files, keys, certificates, passwords and other computer information, as well as information that the Company receives from others under an obligation of confidentiality.

(b) I will not, at any time, without the Company's prior written permission, either during or after my Service Relationship, disclose any Confidential Information to anyone outside of the Company, or use or permit to be used any Confidential Information for any purpose other than the performance of my duties as a service provider of the Company. I will cooperate with the Company and use my best efforts to prevent the unauthorized disclosure of all Confidential Information. I will deliver to the Company all copies of Confidential Information in my possession or control upon the earlier of a request by the Company or termination of my Service Relationship.

(c) Notwithstanding the foregoing, pursuant to 18 U.S.C. Section 1833(b), I shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that: (1) is made in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney, and solely for the purpose of reporting or investigating a suspected violation of law; or (2) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

(d) Notwithstanding anything herein to the contrary, I understand that this Agreement will not (1) prohibit me from making reports of possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of 1934, as amended, or Section 806 of the Sarbanes-Oxley Act of 2002, or of any other whistleblower protection provisions of federal law or regulation, or (2) require notification or prior approval by the Company of any such report; provided that, I am not authorized to disclose communications with counsel that were made for the purpose of receiving legal advice or that contain legal advice or that are protected by the attorney work product or similar privilege.

2. Developments.

(a) All inventions, know-how, knowledge, discoveries, data, technology, designs, innovations and improvements (whether or not patentable and whether or not copyrightable), which are created, invented, developed, conceived, discovered or reduced to practice by me, solely or jointly with others, in the course

of my Service Relationship with the Company (the "Inventions") are the sole property of the Company, and the Company has the right to use any Inventions to develop products, to effect its development, marketing and sales activities and to otherwise freely use such Inventions in the conduct of its business operations. I agree to assign and hereby assign to the Company all of my rights, title and interest in any Inventions and any and all related patents, copyrights, trademarks, trade names, and other industrial and intellectual property rights and applications therefor, in the United States and elsewhere, and appoints any officer of the Company as my duly authorized attorney to execute, file, prosecute and protect the same before any government agency, court or authority. Upon the request of the Company and at the Company' s expense, I will execute such further assignments, documents and other instruments as may be necessary or desirable to fully and completely assign all Inventions to the Company and to assist the Company in applying for, obtaining and enforcing patents or copyrights or other rights in the United States and in any foreign country with respect to any Invention.

(b) I will promptly disclose to the Company all Inventions and will maintain adequate and current written records (in the form of notes, sketches, drawings or in such form as may be specified by the Company) to document the conception and/or first actual reduction to practice of any Invention. Such written records are and remain the sole property of the Company at all times.

(c) If any Invention is not the property of the Company by operation of law, this Agreement or otherwise, I will, and I hereby do, assign to the Company all right, title and interest in such Invention, without further consideration, and will assist the Company and its nominees in every way, at the Company' s expense, to secure, maintain and defend the Company' s rights in such Invention. I will sign all instruments necessary for the filing and prosecution of any applications for, or extension or renewals of, letters patent (or other intellectual property registrations or filings) of the United States or any foreign country which the Company desires to file and relates to any Invention. I hereby irrevocably designate and appoint the Company and its duly authorized officers and agents as my agent and attorney-in-fact (which designation and appointment shall be deemed coupled with an interest and shall survive my death or incapacity), to act on my behalf to execute and file any such applications, extensions or renewals and to do all other lawfully permitted acts to further the prosecution and issuance of such letters patent, other intellectual property registrations or filings or such other similar documents with the same legal force and effect as if executed by me.

(d) I further acknowledge that all original works of authorship which are made by me (solely or jointly with others) in the course of the performance of my Service Relationship and which are protectable by copyright are "works made for hire," as that term is defined in the United States Copyright Act. To the extent any such works of authorship do not qualify as "works made for hire," as that term is defined in the United States Copyright Act, then I will, and I hereby do, assign to the Company all right, title and interest, including copyrights, in such works of authorship.

(e) Attached hereto as Exhibit I is a list of all inventions, modifications, discoveries, designs, developments, improvements, processes, software programs, works of authorship, documentation, formulae, data, techniques, know-how, secrets or intellectual property rights or any interest therein made by me prior to the commencement of my Service Relationship (collectively, the "Prior Inventions"), which belong to me and which relate directly to the business of the Company and which are not assigned to the Company hereunder; (or if no such list is attached, I represent that there are no such Prior Inventions that relate to the business of the Company). If, in the course of my Service Relationship, I incorporate into a Company product, process or machine a Prior Invention owned by me or in which I have an interest, the Company is hereby granted and has a non-exclusive, royalty-free, irrevocable, perpetual, transferable, worldwide license to make, have made, modify, use, sell and otherwise exploit such Prior Invention as part of or in connection with such product, process or machine, or any enhancements or extensions thereof.

3. Nondisparagement and Cooperation. During my Service Relationship and at all times thereafter:

(a) I will not, directly or indirectly, disparage or otherwise take any action that could reasonably be expected to harm the reputation of the Company or any of its products or practices, directors, officers, employees, stockholders, partners or agents. This Section shall not, however, prohibit the Executive from testifying truthfully as a witness in any court proceeding or governmental investigation.

(b) I will cooperate with the Company and its counsel with respect to litigation, investigations, audits, governmental proceedings and all similar matters that relate to events occurring, in whole or in part, during my Service Relationship. The Executive will render such cooperation in a timely manner on reasonable notice from the Company. Following my Service Relationship, the Company will exercise reasonable efforts to limit and schedule the need for my cooperation so as not to materially interfere with my other professional obligations.

4. Survival and Assignment by the Company.

(a) I understand that my obligations under this Agreement will continue in accordance with its express terms regardless of any changes in my title, position, duties, salary, compensation or benefits or other terms and conditions of my Service Relationship. I further understand that my obligations under this Agreement will continue following the termination of my Service Relationship regardless of the manner of such termination and will be binding upon my heirs, executors and administrators.

(b) I acknowledge that the current and future parents, subsidiaries or affiliates of the Company are intended third party beneficiaries of this Agreement. I agree that the Company may assign this Agreement to a successor to or acquirer of any portion of its business or assets, without my consent.

5. Severability. This Agreement shall be interpreted in such a manner as to be effective and valid under applicable law, but if any provision hereof shall be prohibited or invalid under any such law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating or nullifying the remainder of such provision or any other provisions of this Agreement. If any one or more of the provisions contained in this Agreement shall for any reason be held to be excessively broad as to duration, geographical scope, activity or subject, such provision(s) shall be construed by limiting and reducing it so as to be enforceable to the maximum extent permitted by applicable law.

6. No Service Relationship Obligation. I understand that this Agreement does not create an obligation on the Company or any other person to continue my Service Relationship. I acknowledge that my Service Relationship with the Company is at-will and therefore may be terminated by the Company or me at any time and for any reason, with or without cause.

7. Non-Solicitation and Non-Competition.

(a) I agree that during the period of my Service Relationship and for the one year period after my Service Relationship ends for any reason (whether the relationship is terminated by me or the Company, with or without cause), I will not do any of the following, either directly or indirectly, except on behalf of the Company:

(1) solicit, induce, encourage, or participate in soliciting, inducing, or encouraging any employee, contractor, investor, lender, partner or supplier of the Company to terminate or alter his, her or its relationship with the Company;

(2) hire, employ, or engage, or attempt to hire, employ, or engage any person employed or engaged by the Company (or who was employed or engaged by the Company within the preceding 12 months) or discuss any potential employment or engagement with such person, even if I did not initiate the discussion or seek out the contact;

(3) solicit, perform, provide or attempt to perform or provide Competitive Products to any Customer or Potential Customer (as those terms are defined below); or

(4) establish, invest in, promote or perform services for another enterprise engaged anywhere in the world in the development, manufacture or marketing of Competitive Products; provided, however, that my ownership of one percent or less of the outstanding publicly traded capital stock of any company will not violate this paragraph, provided that I have no other relationship with such company. I acknowledge that the Company's business and the market for its products is global in scope.

(b) For purposes of this Agreement:

(1) "Competitive Products" means products or services that are competitive with or similar to products or services of the Company, or products or services that the Company has under development or that are the subject of active planning during my Service Relationship, including, but not limited to products for the treatment or prevention of Friedreich's Ataxia.

(2) "Customer or Potential Customer" means any person or entity who or which, at any time during the preceding two years (while I am still employed or engaged by the Company) or during the two years preceding the end of my Service Relationship (once I am no longer employed or engaged by the Company): (i) contracted for, was billed for or received from the Company any product, service or process; or (ii) was solicited by the Company in an effort in which I was involved, or of which I was or should have been aware, concerning any product, service or process of the Company.

8. Legal and Equitable Remedies.

(a) I agree that it may be impossible to assess the damages caused by my violation of this Agreement or any of its terms. I agree that any threatened or actual violation of this Agreement or any of its terms will constitute immediate and irreparable injury to the Company for which there would be no adequate remedy at law and the Company shall have the right to enforce this Agreement and any of its provisions by injunction, specific performance or other equitable relief, without bond and without prejudice to any other rights and remedies that the Company may have for a breach or threatened breach of this Agreement.

(b) I agree that if the Company is successful in whole or in part in any legal or equitable action against me under this Agreement, the Company shall be entitled to payment of all costs, including reasonable attorney's fees, from me.

(c) If I am found to have been in breach of Section 7 of this Agreement, the restrictions described in that section will be extended by the period equal to the length of time I was in breach of that section.

9. Reasonableness of Restrictions. I have read this entire Agreement, understand it and have had the opportunity to review it with counsel. I agree that this Agreement does not prevent me from earning a living or pursuing my career and that I have the ability to secure other non-competitive employment using my marketable skills. I agree that the restrictions contained in this Agreement, including the duration and scope

thereof, are reasonable, proper and necessary to protect the Company's legitimate business interests, including without limitation the Company's intellectual property rights, Confidential Information and goodwill. I represent and agree that I am entering into this Agreement freely and with knowledge of its contents with the intent to be bound by the Agreement and the restrictions contained in it.

10. Notification of New Employer. In the event that I leave the employ of the Company, I authorize the Company to provide notice of my obligations under this Agreement to my subsequent employer and to any other entity or person to whom I provide or propose to provide services.

11. Governing Law. This Agreement and actions taken hereunder shall be governed by and construed in accordance with the laws of the State of Delaware, applied without regard to conflict of law principles.

[The remainder of this page is intentionally left blank]

IN WITNESS WHEREOF, the undersigned has executed this Confidentiality, Intellectual Property Assignment and Restrictive Covenant Agreement as of the date set forth below.

Signed: /s/ Russell Clayton Date: 5/23/2023
(sign name above)

Print Name: Russell G. Clayton Sr., D.O.

Exhibit I
Prior Inventions

None

Exhibit 31.1

CERTIFICATION

I, Carole S. Ben-Maimon, M.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Larimar Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

1. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
2. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
3. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
4. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

1. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
2. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 10, 2023

/s/ Carole S. Ben-Maimon, M.D.

Carole S. Ben-Maimon, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Michael Celano, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Larimar Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

1. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
2. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
3. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
4. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

1. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
2. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 10, 2023

/s/ Michael Celano

Michael Celano
Chief Financial Officer
(Principal Financial Officer and Accounting Officer)

Exhibit 32.1

CERTIFICATION
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Larimar Therapeutics, Inc. (the "Company"), does hereby certify, to the best of such officer's knowledge, that:

(1) The Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 (the "Report") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 10, 2023

/s/ Carole S. Ben-Maimon, M.D.
Carole S. Ben-Maimon, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 10, 2023

/s/ Michael Celano
Michael Celano
Chief Financial Officer
(Principal Financial and Accounting Officer)